510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k062191

B. Purpose for Submission:

510(k) premarket notification package to manufacture and market the Dimension Vista™ System Drugs of Abuse Positive Control (UDAT CON(+)-KC515) and Negative Control (UDAT CON(-)-KC516).

C. Measurand:

Control Materials for Amphetamine/Methamphetamine, Barbiturate, Benzodiazepines, Cocaine Metabolite, Methadone, Opiates, Phencyclidine, and Cannabinoids.

D. Type of Test:

Control Materials

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension Vista™ Drugs of Abuse Positive Control

Dimension Vista™ Drugs of Abuse Negative Control

G. Regulatory Information:

1. Regulation section:

   862.3280 - Clinical toxicology control material

2. Classification:

   Class I

3. Product code:

Drug mixture control materials (DIF)

4. Panel:

   Toxicology (91)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) for use:

   The Dimension Vista™ System Drugs of Abuse Positive Control is an *in vitro* diagnostic product intended as quality control product for the Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC) methods on the Dimension Vista™ System.

   The Dimension Vista™ System Drugs of Abuse Negative Control is an *in vitro* diagnostic product intended as quality control product for the Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC) methods on the Dimension Vista™ System.

3. Special conditions for use statement(s):

   For prescription use

4. Special instrument requirements:

   Dimension Vista System

I. Device Description:

The Dimension Vista™ System Drugs of Abuse Positive Control is a liquid, multi-analyte, human urine-based product for the following constituents at above the cutoff levels of the methods:

Analyte	Constituent
Amphetamine/Methamphetamine	D-methamphetamine
Barbiturate	Secobarbital
Benzodiazepines	Nordiazepam
Cocaine Metabolite	Benzoylecgonine
Methadone	Methadone

Analyte	Constituent
Opiates	Morphine
Phencyclidine	Phencyclidine
Cannabinoids	11-nor-Δ^9-THC-9 –COOH

The kit consists of six vials which are ready for use (no preparation is required). The volume per vial is 2.5 mL.

The Dimension Vista™ System Drugs of Abuse Negative Control is a liquid, multi-analyte, human urine-based product containing the following constituents below the cutoff levels of the methods:

Analyte	Constituent
Amphetamine/Methamphetamine	D-methamphetamine
Barbiturate	Secobarbital
Benzodiazepines	Nordiazepam
Cocaine Metabolite	Benzoylecgonine
Methadone	Methadone
Opiates	Morphine
Phencyclidine	Phencyclidine
Cannabinoids	11-nor-Δ^9-THC-9 –COOH

The kit consists of six vials which are ready for use (no preparation is required). The volume per vial is 2.5 mL

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Dimension® Drugs of Abuse Positive Control

   Dimension® Drugs of Abuse Negative Control

2. Predicate 510(k) number(s):

   k950138

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Analytes	Amphetamines /Methamphetamines (AMPH), Barbiturates	Amphetamines /Methamphetamines (AMPH), Barbiturates

Similarities		
Item	Device	Predicate
	(BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC).	(BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC).
Form	Liquid	Liquid
Traceability	GC/MS	GC/MS
Matrix	Human urine based	Human urine based
Number of levels	One positive, one negative	One positive, one negative

Differences		
Item	Device	Predicate
Intended use	The Dimension Vista™ System Drugs of Abuse Control is an in vitro diagnostic product intended as quality control product for the Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC) methods on the Dimension VistaTM System.	The Drugs of Abuse Positive Control is an in vitro diagnostic product intended as quality control product for the following methods packaged in Flex® reagent cartridges: Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC).

K. Standard/Guidance Document Referenced (if applicable):

FDA Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final

FDA Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use
FDA Guidance for Industry – Points to Consider Guidance Document on

Assayed and Unassayed Quality Control Material

FDA Guidance for Industry and FDA Staff – Bundling Multiple Devices or Multiple Indications in a Single Submission; Draft

CEN 13640 Stability testing of In-Vitro Diagnostic Devices

ISO 14971:2000 Medical devices -Application of risk management to medical devices

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not Applicable

b. Linearity/assay reportable range:

Not Applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability

The assigned values of the Dimension Vista™ System Drugs of Abuse Positive Control and the Dimension Vista™ System Drugs of Abuse Negative Control are traceable to Gas Chromatography / Mass Spectrometry (GC/MS) Reference Testing.

Value Assignment

Calculated quantities of D-Methamphetamine, Secobarbital, Nordiazepam, Benzoylecgonine, Methadone, Morphine, Phencyclidine, and 11-nor-Δ^9-THC-9-COOH high purity stock solutions are added to drug free normal human urine to target concentrations for each of the Negative and Positive Controls. The Negative and Positive Bulk Products are tested by GC/MS and any analyte that is out of the acceptable GC/MS range is adjusted and retested. Values are assigned to the controls once the GC/MS results are in the acceptable ranges.

Stability

Protocols and acceptance criteria were described and found to be acceptable.

d. Detection limit:

Not Applicable

e. Analytical specificity:

Not Applicable

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable

b. Clinical specificity:

Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

Not Applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.